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Group Art Unit: 1616

### REMARKS

Claims 8-17 are currently pending in the instant application.

In Paper No. 7, the Examiner rejects claims 8-17 under 35 U.S.C. §103(a), as being unpatentable over U.S. Pat. No. 6,261,598 of Runge, *et al.*, (hereinafter referred to as "Runge"), in view of either U.S. Pat. No. 5,976,568 of Riley, (hereinafter referred to as "Riley") or U.S. Pat. No. 6,205,354 of Gellermann, *et al.*, (hereinafter referred to as "Gellermann"). Specifically, the Examiner contends that Runge discloses an oral carotenoid formulation containing 0.5-20 mg of  $\beta$ -carotene, 0.5-20 mg of lycopene and 0.5-20 mg of lutein, dispersed in an edible oil. The Examiner acknowledges that Runge fails to teach the claimed methods of improving the sun protection factor of human skin and inhibiting the aging of human skin. However, the Examiner argues that Riley discloses "carotenoid-containing oral formulations useful for protecting against UV radiation and aging due to the effects of solar radiation." (See, Paper No. 7, p. 2). The Examiner also contends that Gellermann discloses the protection of skin from reactive oxygen species by carotenoids. The Examiner then argues that both Riley and Gellermann suggest that "the claimed combination of carotenoids is effective in protecting the skin from solar radiation . . . ." (*See. id.*). On the basis of these contentions, the Examiner argues that the claimed invention would have been obvious to one of ordinary skill in the art.

Applicants respectfully traverse the Examiner's rejection, along with the contentions and arguments in support thereof for the following reasons.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the cited combination of references. It is well-settled that in order to establish *prima facie* obviousness, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the

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reasonable expectation of success must both be found in the prior art and not in the Applicant's Specification. (M.P.E.P. §2143).

Applicants' claimed invention is directed to methods of improving the sun protection factor of human skin and methods of inhibiting the aging of human skin, the methods comprising: (i) providing a composition comprising (a)  $\beta$ -carotene, (b) lutein and (c) lycopene, in a ratio by weight (a):(b):(c) of from 1:0.5:0.5 to 1:1.5:1.5; and (ii) orally administering the composition to a human. Applicants have surprisingly found that the mixture of these three particular carotenoids in the claimed ratios is particularly well-suited to increasing the sun protection factor of the skin and simultaneously inhibiting the aging of the skin. (See, Applicants' Specification, p. 3, line 26, through p. 4, line 3).

Runge fails to teach the claimed methods, as acknowledged by the Examiner. Runge is directed to food coloring compositions containing  $\beta$ -carotene, lycopene and lutein in various amounts. (See, Runge, col. 3, lines 61-65). Runge does not disclose the use of any of the claimed carotenoids for the purposes of the claimed methods. Moreover, none of the examples set forth in Runge appear to disclose combinations of  $\beta$ -carotene, lycopene and lutein in accordance with the claimed ratios by weight. Accordingly, Applicants submit that not only does Runge fail to teach the claimed invention, Runge further fails to suggest each and every element of the claimed invention and also lacks any teaching or suggestion which would motivate one of ordinary skill in the art to modify its teaching to arrive at the claimed invention.

Neither Riley, nor Gellermann remedies the deficiencies of Runge. Riley is directed to complex, multi-component, modular supplement diets which contain approximately forty ingredients, of which  $\beta$ -carotene, lycopene and lutein are three. However, the ratio of the three components in the compositions of Riley do not appear to be within the claimed ratios. Moreover, while Riley seems to acknowledge that lycopene may have some role in "decreas[ing] ... skin damage secondary to ultraviolet exposure", Riley fails to teach or suggest that combinations of the claimed components in the claimed ratios by weight can be used in accordance with the methods of the claimed invention. There is no indication in Riley that combinations of  $\beta$ -carotene, lycopene and lutein will increase the sun protection factor of the skin. Additionally, Riley does not appear to exemplify amounts of lycopene and lutein effective

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in achieving the skin protecting effects of the claimed invention. Finally, the mere indication in Gellermann that carotenoids can protect the skin from reactive oxygen species which can be formed upon excessive exposure to UV light, does not equate to a teaching or suggestion that combinations of  $\beta$ -carotene, lycopene and lutein in the claimed ratios by weight will increase the sun protection factor of the skin or inhibit aging.

Given the lack of any teaching or suggestion to combine and modify the references to arrive at the claimed invention, and the fact that the references otherwise fail to teach or suggest each and every element of the claimed invention, one of ordinary skill in the art would have no reasonable expectation of successfully achieving the claimed invention based on the teachings of the cited combination.

Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied. Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejection and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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